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(71) Applicant: **NOVO NORDISK A/S**

2880 Bagsvaerd (DK)

(72) Inventors:

• **KLITMOSE, Lars Peter**

2820, Gentofte (DK)

• **HANSEN, Henrik, Egesborg**

2900, Hellerup (DK)

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(54) Injection device with electronic presentation of set doses

(57) An injection device has signal generators (11, 12, 13, 14) which are connected to operative elements (8, 3, 5, 4) of the device and which give off signals which represents the operative condition of the device. The signals are sent to an electronic circuit which controls a presentation of the operational condition of the device and presents operational conditions, which are defined as not allowed, as error indications by switching off the display presenting the operational condition of the device. The number of signals from each generator is counted and a number of operations exceeding a pre-set number for the signal generator in question is interpreted as representing a not allowed operational condition.

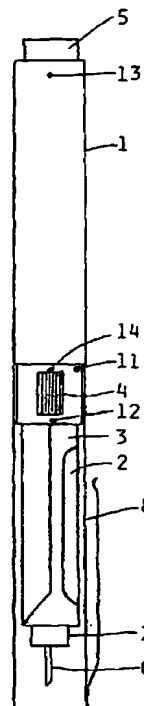


Fig. 1

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Description

[0001] The invention relates to injection devices for the injection of set doses of a medicine, the operational condition of the device being electronically presented by a circuit which receives a pattern of input signals from signal generators connected to the operative elements of the device.

[0002] Such an injection device may have the shape of a device comprising a dose setting wheel and an injection button and a protective cap covering at least a needle receiving part of the device and possibly the dose setting wheel. The electronic presentation usually has the shape of an electronic display, but also a speech circuit may be used which in speech summarize the condition of the device. Also a electro mechanic device presenting a tactile resume may be imagined.

[0003] The generators connected to the operative elements of the device may be switches switching on and off a current or they may be active current generators. Generators of the switch type may be connected to the protective cap or the injection push button to indicate one of two alternative positions, i.e. the cap on or the cap off, or the push button projecting or pressed home.

[0004] A generator of an active type which itself produces a current when activated may be connected to the dose setting wheel to provide current signals reflecting the turning of this wheel, e.g. a pulse per unit set by turning the wheel and the pulse having a polarity indicating whether the dose setting is increased or decreased by turning of the wheel. The dose setting signals may also be provided by operating a number of switches.

[0005] The use of electronic presentation of the device parameters makes it possible to use a display with large digits in opposition to mechanical displays by which the movements of the dose setting wheel and a plunger operating a piston in an ampoule with the medicine to be injected set narrow limits on the size of the displayed digits.

[0006] The electronic presentation depends on electric switches and generators which may, e.g. due to wear, fail without warning and course a false electric signal and consequently a false displaying. By mechanical devices wear may or may not reveal itself by the device being still more rickety.

[0007] Consequently it is an object of the invention to provide a device by which unreliable electrical or mechanical components are detected before they cause a wrong dosing of the medicine injected by the device.

[0008] This may be obtained by a device as the one described in the opening paragraph of this specification, which device is characterized in that it comprises a circuit which receives input signals from signal generators connected to operative elements of the device and gives off a signal which represents the operational condition of the device and controls a presentation of said operational condition.

[0009] According to the invention operational conditions which are defined as not allowed may be presented as an error indication. Further according to the invention at least one of the signal generators may be an active generator generating electric signals.

[0010] According to an embodiment of the invention the circuit may comprise a storage in which is stored the signal patterns for all allowed conditions of the device, the signals from the signal generators are frequently compared with the stored signal patterns, and if the signal pattern is not found among the allowed patterns an error indication is made.

[0011] An error may be indicated by switching off the presentation of the operational condition of the device.

[0012] The allowed signal patterns are such patterns which occurs during normal not faulty use of the device. Say that the device has a dose setting wheel which is covered by the protective cap when this cap is mounted on the device. In that case a pattern of signals comprising a signal indicating that the cap is on and another signal indicating that the dose setting wheel is operated will not be allowed as the dose setting wheel may not be operated when it is covered by the cap as this represent an obvious logical discrepancy. If locks are provided by which it is intended to exclude concomitant operation of two of the elements of the syringe, then signals indicating that these two elements are nevertheless operated concomitantly will cause an indication of error.

[0013] In an embodiment of the device according to the invention the circuit may be designed to count the number of signals send from each of the signal generators, to compare these numbers with set values stored in the circuit, and to give off a signal when one of the numbers exceed the set value for the signal generator in question, which signal provokes an error indication. By this feature it may be ensured that the device is only used for a number of operations and that the device is replaced by a new one before dysfunction due to wear becomes probable.

[0014] If a switch is worn to an extent which makes its stability questionable this will be manifested by the fact that the switch appears as off when it should be on or visa versa which soon will lead to a not allowed signal pattern. When this pattern is detected as not being among the allowed patterns the circuit will turn off the electronic presentation of parameters and the device is made not useable.

[0015] As a not allowed signal pattern may be induced by an event which is not related to the condition of the device, e.g. a transient electromagnetic field caused by any electric apparatus in the vicinity, the circuit may, when it turns off the electronic presentation, be reset to allow this presentation again. If the turning off of the electronic presentation is due to an event outside the device, the device will be usable again after the resetting but if the not allowed signal pattern was caused by a failing switch, this switch will soon fail again and turn off the electronic presentation.

[0016] Another check of the function may be obtained by summing up the number of doses injected since the ampoule was changed. If the accumulated dose exceeds the total content in a new ampoule an error is reported, e.g. by turning off the electronic presentation.

[0017] Recognizing that the switches and generators have a greatly enhanced probability of failing when they have been used a number of times the circuit may be designed to count the number of signals sent from each of the signal generators, to compare these numbers with set values stored in the circuit, and to give off a signal when one of the numbers exceed the set value for the signal generator in question, which signal forms a part of the signal pattern representing the condition of the device and makes this a not allowed pattern. Consequently it cause a disabling of the device when the counts for one of the signal generators reach the number set for that generator.

[0018] As the disabling of the device on the basis of the counting of signals from the signal generators is predictable, a warning may be presented to the user when one of the generators has produced a number of signals near the set number for this generator. In this way the user may avoid the inconvenience of a suddenly failing device.

[0019] To further avoid sudden failing of the device, the battery condition is currently monitored and a low battery is indicated some time before the battery is totally exhausted.

[0020] The failing of the switches and generators may not be foreseen and will cause a sudden disabling of the device. For emergency the circuit may then be reset and the device may be used a few times more unless the switches have become so unstable that the device is at once disabled again.

[0021] In the following an embodiment of the invention is described with references to the drawing in which

Figure 1 shows schematically an injection device with electrical signal generators

Figure 2 a graph showing how operations brings an injection device according to the invention from one condition to another.

[0022] The device in figure 1 comprises the following operative members:

- a dose setting wheel 4 by the turning of which a dose may be set
- an injection button 5
- a lid 3 covering a cartridge 2 accommodated in a housing 1
- a removable protective cap 8 covering the dose setting wheel 4 and the lid 3.

[0023] Further the following mechanical locks are established:

- when button 5 is pressed home it is locked in this position. The button 5 is released when the dose setting wheel 4 is operated. Consequently the button 5 cannot be in its pressed home position during setting of a dose; if the button 5 is maintained in its pressed home position, the dose setting wheel 4 cannot be turned. The correct function of the lock is checked by the electronics as previously explained by interpreting a signal indicating an operation which should be locked as not allowed.
- the dose setting wheel 4 is locked when the lid 3 is open. This locking is appropriate as the opening of the lid 3 as a rule is performed to change the cartridge 2. During the changing of the cartridge 2 a piston rod, through which a movement corresponding to the set dose is transferred to a piston in the cartridge when the button 5 is pressed home, have to be moved backward to make space for the new full cartridge and consequently the coupling between the dose setting mechanism and the piston rod is released to make the piston rod freely movable. When said coupling is released a turning of the dose setting wheel 4 will activate the generator coupled to said wheel and make the user think that he sets a dose, but due to the released coupling no dose or a wrong dose will be injected by the operation of the button 5. To avoid such a malfunction the said mechanic lock is established. Also by this lock the correct function is checked by the electronics by interpreting a signal indicating an operation which should be locked as not allowed.

[0024] When a dose is set it may be injected by pressing the button 5. The injection takes place through a needle 6 which can be mounted on the syringe by a needle hub 7 carrying the needle.

[0025] The button 5, the lid 3, and the cap 8 are each collaborating with a switch indicated by the points 13, 12 and 11, respectively. Each switch has two positions, ON or OFF, so that the position of the switch is representative for the condition of the element collaborating with the switch in question. These conditions are:

- The cap on or off
- the button down (pressed home) or up (not pressed home)

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- the lid closed or not closed (open)

[0026] The eight conditions defined by the positions of the above mentioned three switches are shown in table I.

[0027] Turning of the dose setting wheel 4 will result in signals from a signal generator 14 cooperating with the dose setting wheel to give off a number of pulses corresponding to the extent of the turning of the wheel and having a polarity by which it is indicated whether the turning of the wheel 4 results in an increase or a decrease of the number of set units.

TABLE I

Condition	I	II	III	IV	V	VI	VII	VIII
Cap	on	on	on	on	off	off	off	off
Button	down	down	up	up	down	down	up	up
Lid	open	clsd	open	clsd	open	clsd	open	clsd
Allowed	-	+	-	+	+	+	+	+
Dose sett.	-	-	-	-	-	-	-	+

[0028] As it is seen from table I the conditions I and III are not allowed because the lid cannot be open when the cap is on.

[0029] In the conditions allowed for the switches dose setting signals may only be accepted in condition VIII. With the switches in condition I-IV the dose setting wheel 4 cannot be operated because the cap 8 is on. In condition V and VI the dose setting wheel may not be operated because the button 5 is in its home pressed position; if a dose setting signal is nevertheless received by the circuit it will indicate malfunction of the lock locking the dose setting wheel when the button is down.

[0030] A dose setting signal when the switches are in condition VII will indicate malfunction of the locking of the dose setting wheel when the lid is open.

[0031] The switches may each serve a purpose of its own. The cap on/off switch 11 may switch off a display to save battery when the cap is on. Further the activation of the switch 11 when the cap is demounted may start a display test by which all segments in the display are shortly activated to allow the user to know if all the segments are operational. The button down/up switch 13 may indicate when the button is pressed home and a injection has been completed, if the button is not fully pressed home the injection is not completed and the set dose has not been injected. Further this switch may reset and start a stop watch indicating the time passed since the latest injection. The lid open/closed switch 12 indicates the possible change of cartridge and deletes a set dose from the electronic presentation, e.g. a display, as a cartridge shifting procedure ensuring that the piston rod abuts the piston of the new cartridge has to be performed before a dose can be set. The opening and closing of the lid also may reset a possible malfunction reaction of the circuit to make the device function again if the malfunction reaction was due to an environmental event, e.g. a transient electromagnetic field, whereas the malfunction reaction will soon occur again if it was due to malfunction of the device itself.

[0032] The following actions may be performed

- a₁ The cap may be removed
- a₂ The cap may be replaced
- a₃ The ampoule lid may be opened partially
- a₄ The ampoule lid may be opened fully
- a₅ The ampoule lid may be closed partly
- a₆ The ampoule lid may be closed fully
- a₇ The setting of the dose may be increased
- a₈ The setting of the dose may be decreased
- a₉ The injection button may be partly depressed or released
- a₁₀ The injection button may be fully depressed
- a₁₁ The injection button may be released

[0033] In figure 1 it is illustrated how the actions either leave the switches unchanged or bring them from one of their six allowed combinations to another.

[0034] When the device is stored in condition II with the cap on, only one transaction is possible; the cap may be removed, a₁, which will bring the device to condition VI. From condition VI the device may either be brought back to condition II by remounting the cap, a₂, or it may be brought into condition V by opening the ampoule lid partially or fully, transactions a₃ or a₄, respectively, or into condition VIII by releasing the injection button, a₁₁.

[0035] It shall be noticed that the descriptions of the conditions of the cap 8, lid 3, and button 5 are

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1. The cap on or not on
2. The lid closed or not closed
3. The button fully depressed or not fully depressed.

5 [0036] This may be interpreted so that when the cap is only almost on it is OFF, when the lid is not fully closed it is OPEN, and when the button is not fully depressed it is UP.

[0037] In condition V the lid may be opened or closed more or less, as long as it is not fully closed the device remains in condition V. In the same way the device remains in condition VII as long as the lid is not fully closed, a_6 , or the injection button is not fully depressed, a_{10} .

10 [0038] Due to the provision of a mechanical lock the dose setting can only be performed when the device is in condition VIII and consequently operation of the dose setting wheel should not bring the device out of condition VIII. If dose setting signals are received with the switches in another condition it is interpreted as an indication of malfunction.

[0039] It shall be noticed that in other embodiments of the device other locks and switches may be provided controlling other functions of the syringe. E.g. in a preferred embodiment the condition VII is made a not allowed condition by the provision of a lock which prevent the lid from being opened when the button is up and correspondingly prevent the button from coming up when the lid is open. To illustrate the possible conditions of such an embodiment not only condition VII, but also the transactions a_3 and a_{11} leading to this condition and the transactions a_6 and a_{10} leading away from condition VII to the conditions VIII and V, respectively, should be deleted in figure 2.

20 Examples of the invention

[0040]

25 A. An injection device comprising a circuit which receives input signals from signal generators connected to operative elements of the device and gives off a signal which represents the operational condition of the device and controls a presentation of said operational condition.

B. A device according example A, wherein operational conditions which are defined as not allowed are presented as an error indication.

30 C. A device according to examples A or B, wherein at least one of the signal generators is an electric switch with an off and an on position which switch turns off or on an electric current.

35 D. A device according to example A, B or C, wherein at least one of the signal generators is an active generator generating electric signals.

E. A device according to example B, wherein the circuit comprises a storage in which is stored all patterns of input signals which corresponds to allowed conditions of the device,
40 the pattern of the signals from the signal generators are frequently compared with the stored signal patterns, and if the signal pattern is not found among the allowed patterns, an error indication is made.

45 F. A device according to anyone of the preceding examples, wherein the circuit is designed to count the number of signals send from each of the signal generators, to compare these numbers with set values stored in the circuit, and to give off a signal when one of the numbers exceed the set value for the signal generator in question, which signal provokes an error indication.

G. A device according to anyone of the preceding examples, wherein an error indication is made by switching off the presentation of the operational condition of the device.

50 H. A device according to example G, wherein the circuit, when it turns off the electronic presentation, can be reset to allow this presentation.

55 **Claims**

1. An injection device comprising:

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a plurality of operative elements (8, 3, 5, 4) for setting and injecting of set doses of medicine, signal generators (11, 12, 13, 14) connected to at least one of said operative elements (8, 3, 5, 4) to generate output signals representing operating conditions of said at least one operative elements (8, 3, 5, 4), and an electronic circuit coupled to said signal generators (11, 12, 13, 14) for receiving said output signals, and generating a signal which controls a presentation of said operating conditions, **characterised in that**, said electronic circuit is designed to count the number of signals sent from at least one of said signal generators (11, 12, 13, 14) to compare such numbers with stored values, and to generate a signal when a corresponding number is equal to or exceeds its corresponding stored value.

2. A device according to claim 1, **characterised in that** said device includes a housing (1) and that said operative elements (8, 3, 5, 4) are selected as one or more operative elements selected from the group consisting of:
 - a protective cap (8) which can selectively be mounted on said housing (1),
 - a lid (3) which can selectively be disengaged from said housing (1) for changing cartridges (2), and
 - an injection button (5).
3. A device according to claim 2, **characterised in that** said operative elements (8, 3, 5, 4) further include a dose-setting wheel (4) and that said device includes a signal generator (14) associated with said dose-setting wheel (4).
4. A device according to any of the preceding claims, **characterised in that** at least one of said signal generators (11, 12, 13, 14) includes an electric switch having on and off positions.
5. A device according to any of the preceding claims, **characterised in that** at least one of said signal generators (11, 12, 13, 14) is an active generator.
6. A device according any of the preceding claims, **characterised in that** said device further includes a means for generating an external presentation of the operating condition of the device and for switching off such external presentation when an error condition is detected.
7. A device according to claim 6, **characterised in that** it further includes a means for resetting the means for switching off such external presentation.
8. A device according to any of the claims 1-5, **characterised in that** said electronic circuit further comprises means for generating an external presentation of the operating condition of the device and means for indicating an error indication responsive to said signal being generated when one of said corresponding number is equal to or exceeds its corresponding stored value.
9. A device according to any of the preceding claims, **characterised in that** said electronic circuit further comprises means for generating a warning signal when one of said counted numbers are near the corresponding stored number.

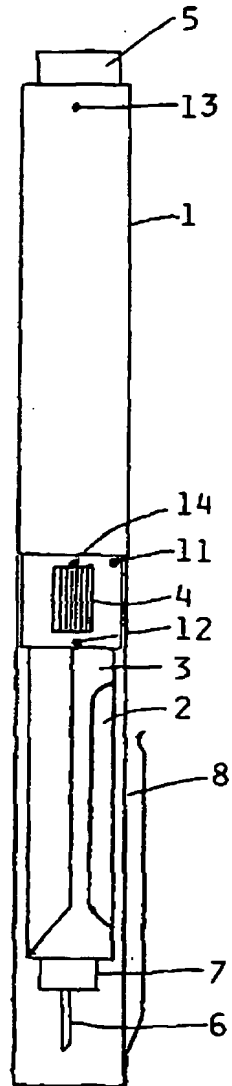


Fig. 1

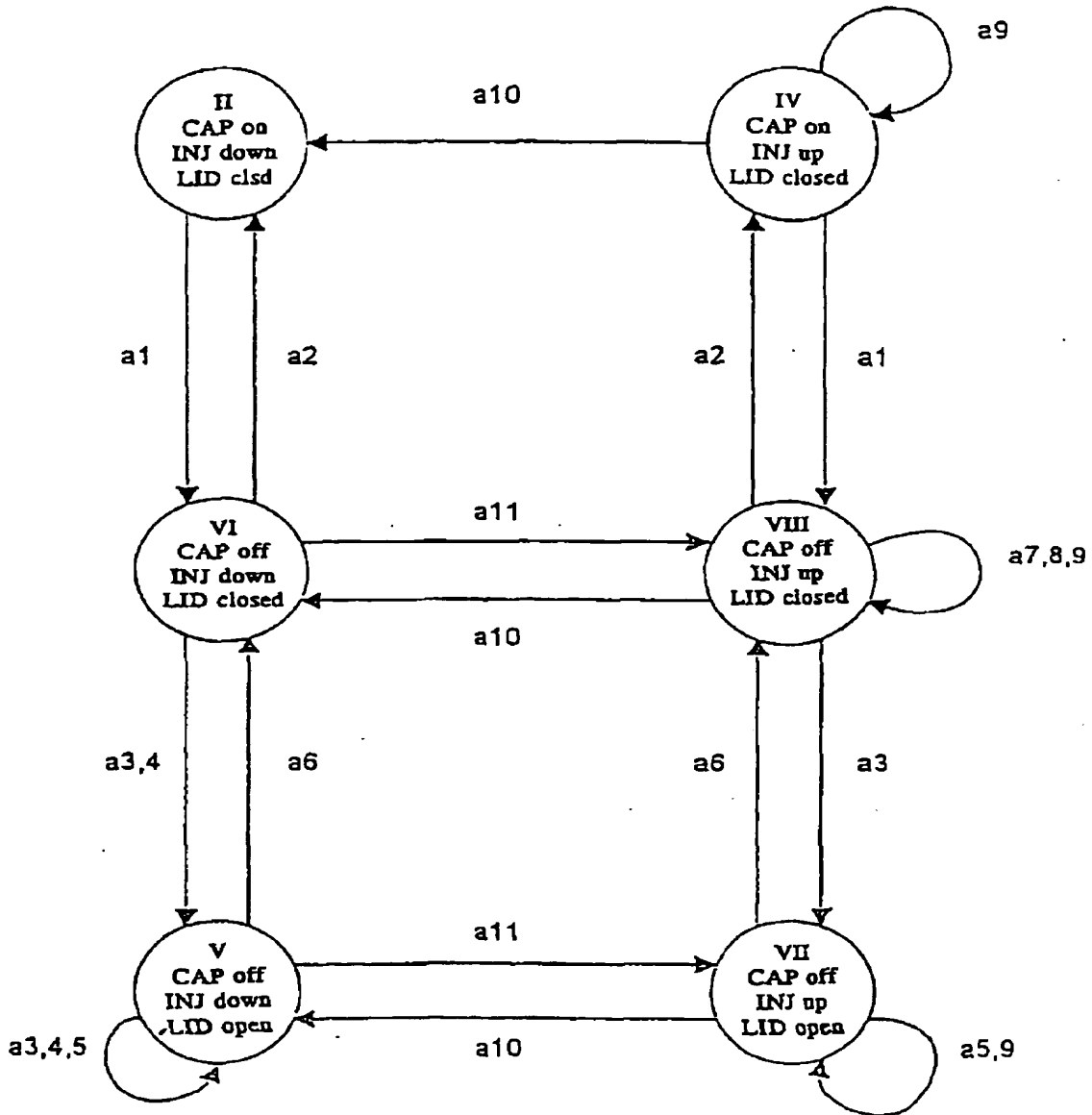


Fig. 2



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EUROPEAN SEARCH REPORT

Application Number
EP 06 10 0166

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	WO 90/09202 A (NOVO-NORDISK A/S) 23 August 1990 (1990-08-23) * the whole document *	1-9	INV. A61M5/24
X	US 4 919 596 A (SLATE ET AL) 24 April 1990 (1990-04-24) * column 7, paragraph 52 - column 9, paragraph 3 *	1-9	
X	US 5 254 096 A (RONDELET ET AL) 19 October 1993 (1993-10-19) * column 3, paragraph 33-42 * * column 6, paragraph 23-34 *	1-9	
			TECHNICAL FIELDS SEARCHED (IPC)
			A61M
The present search report has been drawn up for all claims			
Place of search Munich		Date of completion of the search 18 April 2006	Examiner Krassow, H
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

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**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

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This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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18-04-2006

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9009202	A	23-08-1990	AU 5106290 A	05-09-1990
			DK 68789 A	15-08-1990
			GR 90100107 A	28-06-1991
			PT 93150 A	15-10-1991
			ZA 9001105 A	28-11-1990

US 4919596	A	24-04-1990	NONE	

US 5254096	A	19-10-1993	DE 69315158 D1	18-12-1997
			DE 69315158 T2	12-03-1998
			EP 0589328 A2	30-03-1994
			JP 2610385 B2	14-05-1997
			JP 6190037 A	12-07-1994

EPO FORM P0459

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